

## ***FACT SHEET FOR PATIENTS: UNDERSTANDING SWINE INFLUENZA KIT TEST RESULTS***

April 26, 2009

An emergency has been declared by the Secretary of Health and Human Services because of the 2009 outbreak of swine influenza (swine flu). The Food and Drug Administration (FDA) has authorized the emergency use of Swine Influenza Test Kit to test for the presence of swine flu virus. This authorization will terminate on April 26, 2010 or when the emergency has ceased to exist, whichever is earlier. The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the emergency use of Swine Influenza RT-PCR assay.

### **Why was my sample tested using the Swine Influenza Test Kit?**

There are no FDA cleared or approved tests that can identify swine flu virus. Therefore, your sample was tested using the Swine Influenza Test Kit because you may have been exposed to the swine flu virus. This test could help to determine whether you are infected with the swine flu virus, so that public health officials could quickly identify a case and limit its spread. The results of this test, along with other information, may also help your doctor take better care of you.

### **What is swine flu?**

Swine flu is a respiratory disease of pigs caused by type A influenza virus that regularly causes outbreaks of influenza in pigs. Human cases of swine flu virus infection have been identified in the United States and internationally. CDC has determined that this virus is contagious and is spreading from human to human. Like seasonal flu, swine flu in humans can vary in severity from mild to severe.

### **What is the Swine Influenza Test Kit?**

The Swine Influenza Test Kit is a sensitive test to detect the swine flu virus. The FDA has not cleared or approved this test. The FDA has agreed that we can use this test under an Emergency Use Authorization. We don't know for sure if this test can identify all people who may get sick with swine flu.

### **What are the known risks and benefits of Swine Influenza Test Kit?**

The results of this test from nasopharyngeal or nasal swab, along with other information, can help your doctor take better care of you. Knowing your test results may help you to prevent the spread of the virus to your family or others. There may be no other benefits to you from this test.

### **If this test is positive, does that mean that I have swine flu?**

Yes, though there is a very small chance that this test can give a result that is wrong (false positive), it is not likely. If your result from this test is positive, your doctor may decide how to care for you based on the test results along with other factors.

### **If this test is negative, does that mean that I do not have swine flu?**

If this test is negative, you may not be sick, or you may be sick with something that is not swine flu. There is a small chance that this can give a result that is wrong (false negative). A false negative result should not affect your care. No changes in your medical care or how you interact with other people should be solely based on a negative result.

\*Any significant new findings observed during the course of the emergency use of Swine Influenza Test Kit will be made available at <http://www.cdc.gov/swineflu/>.